Consumers for Dental Choice
1616 H St., N.W., 8th floor
Washington, DC 20006
Ph. 202.347-9112; fax 347-9114
www.toxicteeth.org

Food and Drug Administration
C/O Document
(HFA-305)
5630 Fishers Lane
Rockville Maryland 20852

September 12, 2002

Re: O1N- 0067: Request for a Stay of Rule Making and Alternatively a Request for an Enlargement of Time

Dear Sir or Madam:

In this rule-making, the FDA has treated the statutory requirements for public input for its rule-making as a nuisance, a mere formality of procedural steps to ratify its pre-determined position.

- At the outset of the rule-making, the FDA boldly announced that mercury fillings are safe, a matter seized on (and promoted in its news releases) as the final word for its ally in this process, the American Dental Association.

- The FDA saw no reason to convene an Advisory Panel to examine the last seven years of the research, instead relying on an out-of-date group which last met in 1995.

The FDA then proceeded to act as if, yes, its final word would simply be ratified through this rule making, as it shielded itself from serious public comment.

- Web site, not e-mail address: For those wishing to send an e-mail, the FDA gave not an e-mail address but a web site! For those member of the public not fully computer literate (most of us over 21), it would be simple to give an e-mail address. Instead, the consumer must go to the web site.

- No listing of this rule, despite over 60 listings: Upon arriving at the web site, the consumer sees about 64 proposed FDA matters for public comments. The mercury dental fillings rule is not one of them! The public would not be able to learn the rule number from

the FDA listing. It would not see it there at all, from the scrolled listing. It is further evidence that the FDA would prefer to hear from organized dentistry only – the only category of supporters it has for supporting putting mercury into children's mouths – and not hear from the general public, whose comments (by those who can work through this labyrinth) have been almost uniformly adverse.

- False zip code: For those wishing to comment in a public hearing, the FDA said no, there would be no public hearing.

- Outflanking Congress: For those wishing to ask their Members of Congress to enact H.R. 4163, to ban mercury filings for children and pregnant and nursing women, and to have strong warnings to all, the FDA is rushing through its rule making before Congress can act. Indeed, one of the bill's sponsors, Congressman Burton, is having hearings of his Government Reform Committee, but the FDA is closing the record before those hearings occur. In deference to the United States Congress, the Food and Drug Administration should hold in abeyance it's proceeding i.e. rule making, in order both the FDA and the public may benefit from the wisdom of these Congressional hearings.

- Attempting pre-emption: For those who wish to enact state consumer protection laws to inform the public of the health and environmental risks of mercury fillings, the FDA appears to be engaging in a strong-arming process of pre-empting those laws, to the utter delight of organized dentistry but to the harm of consumers. It should be noted, and the FDA well knows, that the American Dental Association promotes these fillings as "silver," a cause of great deception to the public, kept unaware that such fillings are mainly mercury. The FDA's response is to rush to the side of organized dentistry, try to pre-empt the laws, and keep the public in the dark about grams of mercury going into their children's mouths.

There is another major problem: the FDA has never responded to FOIA requests essential for public comment.

Personnel from the FDA have not yet responded to inquiries pertaining to information presently in their possession which is relevant and essential to Docket No. 010067 i.e. Docket Numbers 9890182 and 0065 and Docket No. 00N-1665 and info pertaining to DMPS, List of Bulk Drugs, which are in procession of the FDA Adverse Compound

Drug Team, and Consumer Safety Officers, located at 7520 Standish Place, Room 200 Rockville, Maryland 20855.

The public has a right to know about this information within the FDA's possession and it should be submitted to Docket No. 01N-0067. All further action by the FDA should stayed until this process has been completed by the FDA Consumer Safety Officers.

In light of the foregoing reasons we request a stay of all further proceedings by the Food and Drug Administration in regard to mercury as it relates to dental amalgam or in the alternative a 45-day enlargement of time in which to file and guarantee the receipt of public comment.

Respectfully submitted,

Lindell Tinsley
Project Director
Consumers for Dental Choice

CC: Charles G. Brown, Esq.
Mary Ann Newell, Manager of Files
Joseph Sheehan

FAX COVER SHEET

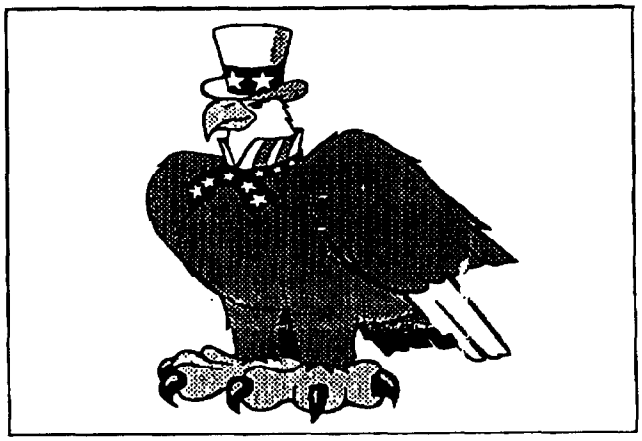
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF HEALTH AND INDUSTRY PROGRAMS
1350 Piccard Dr.
ROCKVILLE, MARYLAND 20850 USA
TELEPHONE: (301) 594-4765

DATE: 9/19/02

TO: Jennie Butler

COMPANY: DOCKETS!

TELEPHONE:



FAX NUMBER: 7-6870

FROM: Ruth Fischer OIN-0067

TELEPHONE: 7-2960

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MESSAGE